§ 886.4100 Radiofrequency electrosurgical cautery apparatus.

(a) *Identification.* A radiofrequency electrosurgical cautery apparatus is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by a high frequency electric current.

(b) *Classification.* Class II.

§ 886.4115 Thermal cautery unit.

(a) *Identification.* A thermal cautery unit is an AC-powered or battery-powered device intended for use during ocular surgery to coagulate tissue or arrest bleeding by heat conducted through a wire tip.

(b) *Classification.* Class II.

§ 886.4150 Vitreous aspiration and cutting instrument.

(a) *Identification.* A vitreous aspiration and cutting instrument is an electrically powered device, which may use ultrasound, intended to remove vitreous matter from the vitreous cavity or remove a crystalline lens.

(b) *Classification.* Class II.

§ 886.4155 Scleral plug.

(a) *Identification.* A scleral plug is a prescription device intended to provide temporary closure of a scleral incision during an ophthalmic surgical procedure. These plugs prevent intraocular fluid and pressure loss when instruments are withdrawn from the eye. Scleral plugs include a head portion remaining above the sclera, which can be gripped for insertion and removal, and a shaft that fits inside the scleral incision. Scleral plugs are removed before completing the surgery.

(b) *Classification.* Class II (special controls). The special controls for the scleral plug are as follows:

(1) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9 if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating. The special controls for the surgical grade stainless steel scleral plug (with or without a gold, silver, or titanium coating) are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible; and

(iii) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

(2) The device is not exempt from premarket notification procedures if it is composed of a material other than surgical grade stainless steel (with or without a gold, silver, or titanium coating). The special controls for scleral plugs made of other materials are:

(i) The device must be demonstrated to be sterile during the labeled shelf life;

(ii) The device must be demonstrated to be biocompatible;

(iii) Characterization of the device materials must be performed;

(iv) Performance data must demonstrate acceptable mechanical properties under simulated clinical use conditions including insertion and removal of the device;

(v) Performance data must demonstrate adequately low levels of the extractables or residues from manufacturing (or processing) of the device; and

(vi) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

[78 FR 68715, Nov. 15, 2013]

§ 886.4170 Cryophthalmic unit.

(a) *Identification.* A cryophthalmic unit is a device that is a probe with a small tip that becomes extremely cold through the controlled use of a refrigerant or gas. The device may be AC-powered. The device is intended to remove cataracts by the formation of an adherent ice ball in the lens, to freeze the eye and adjunct parts for surgical removal of scars, and to freeze tumors.

(b) *Classification.* Class II.

§ 886.4230 Ophthalmic knife test drum.

(a) *Identification.* An ophthalmic knife test drum is a device intended to

test the keenness of ophthalmic surgical knives to determine whether resharpening is needed.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35606, Sept. 14, 1988; 66 FR 38813, July 25, 2001]

§ 886.4250 Ophthalmic electrolysis unit.

(a) *Identification.* An ophthalmic electrolysis unit is an AC-powered or battery-powered device intended to destroy ocular hair follicles by applying a galvanic electrical current.

(b) *Classification.* Class I for the battery-powered device. Class II for the AC-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48443, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38813, July 25, 2001]

§ 886.4270 Intraocular gas.

(a) *Identification.* An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4275 Intraocular fluid.

(a) *Identification.* An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal reattachment.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4280 Intraocular pressure measuring device.

(a) *Identification.* An intraocular pressure measuring device is a manual or AC-powered device intended to measure intraocular pressure. Also included are any devices found by FDA to be substantially equivalent to such devices. Accessories for the device may include calibrators or recorders. The device is intended for use in the diagnosis of glaucoma.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 886.3.

§ 886.4300 Intraocular lens guide.

(a) *Identification.* An intraocular lens guide is a device intended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.

(b) *Classification.* Class I (general controls). Except when used as folders or injectors for soft or foldable intraocular lenses, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 65 FR 2321, 2000]

§ 886.4335 Operating headlamp.

(a) *Identification.* An operating headlamp is an AC-powered or battery-powered device intended to be worn on the user's head to provide a light source to aid visualization during surgical, diagnostic, or therapeutic procedures.

(b) *Classification.* Class I for the battery-powered device. Class II for the